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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,952	04/05/2001	Olivier Lavergne	427.046	9561

7590 12/20/2001

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[REDACTED] EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
1625	b

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/806,952	LAVERGNE ET AL.
	Examiner	Art Unit
	RITA J. DESAI	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- if the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-12 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-12, 17-23 and 25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,5,24 and 26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Lack of Unity/Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 6-8, 10-12, 19-23 and 25 , drawn to a compound of formula Ia .

Group II, claims 17 and 18 drawn to a compound and a process of making a compound M.

Group III, claims 24, 4,5, and 26 , drawn to compounds of formula IIa .

Group IV, claims 9 and 11, drawn to a process of forming compounds of formula III.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group II and Group IV are drawn to a compound and process of making a compound M and III.

Compound M is a starting material for the preparation of compounds of formula I. Its core is Not the same i.e. it does not have a common core .

Group I and II are drawn to similar compounds but the scope is different. Claim 23 in Group I is drawn to compounds of a formula Ia and also individual compounds which may be outside the scope of formula Ia.

A preliminary search of the core gave numerous hits
L5 5 SEA SSS SAM L4

=> s 14 ful

FULL SEARCH INITIATED 15:09:30 FILE 'REGISTRY'
FULL SCREEN SEARCH COMPLETED - 354 TO ITERATE

100.0% PROCESSED 354 ITERATIONS 197 ANSWERS
SEARCH TIME: 00.00.01

L6 197 SEA SSS FUL L4

indicating that these compounds do not have a distinguishing portion over the prior art.

(f) "Markush Practice." The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, **the commonly shared structure constitutes a structurally distinctive portion in view of the existing prior art.** The structural element may be a single component or a combination of individual components linked together.

If applicant's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants preserve their right to file a divisional on the canceled non elected subject matter,

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without prejudice, in due course.

During a telephone conversation with Mr C. Musserlain on 12/12/2001 a provisional election was made with traverse to prosecute the invention of Group II , claims 4, 5, 24 and 25 . Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-12, 17-23, 25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites medicament, which is not a accepted US terminology. Applicant is required to change it to a pharmaceutical composition.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 4,5,24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Curran et al US 6207832.

Curran et al '832 discloses the compounds of the invention. See formula I , wherein R5 is an alkyl, R6 is a Si containing group, R1-R4 is a hydrogen , halogen, or another group.

See compounds in lines 35-50 column 13. Also see claims.

Claims 4, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bigg et al US 5981542.

Bigg et al discloses the camptothecin analogs with the seven membered ring with an oxygen. See formula II wherein all the R's are hydrogen and R1 is an alkyl group, column 9 line 30. Claim 1, compound in column 40, Claim 11 .

The reference clearly discloses the oxepino indolizino quinoline dione.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 24 and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Biggs et al WO 97/00876.

Biggs '876 discloses the compounds of the claimed invention wherein R1 is an alkyl and all the R's are hydrogen. See formula I page 3 and claims 1 ,2.

These are all pharmaceutical compositions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/00876.

Scope and Content of Prior Art MPEP 2141.01

The reference clearly teaches the camptothecin analogs of the formula IIa of the application. The compounds read on the claims when R1 is an alkyl and all other R's are hydrogen. The reference also discloses various substituents such as halogen, and R6 being a hydrogen or alkyl group substituted or unsubstituted by various different groups, including aryls.

Difference Between the Prior Art and the Claims MPEP 2141.02

The reference discloses various combination of the substituents.

Prima Facie Obviousness Rational and Motivation MPEP 2142-2143

One of skill in the art would have been motivated and found it obvious to make the different substituents as described by the genus of the reference to obtain the compounds of the instant invention.

Claims 4, 5, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curran et al US 6207832.

Scope and Content of Prior Art MPEP 2141.01

The reference clearly discloses the the compounds of the invention . see formula I . it also discloses the trimethylsilyl group of the invention.

Difference Between the Prior Art and the Claims MPEP 2141.02

The reference discloses some of the combination of the substituents of the invention.

Prima Facie Obviousness Rational and Motivation MPEP 2142-2143

One of skill in the art would be motivated and would have found it obvious to modify the compounds by mixing the substituents to obtain some of the compounds of the application.

Conclusion

The claims 4, 5, 24 and 26 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R.D.
December 13, 2001

Alan L Rotman
ALAN L ROTMAN
PRIMARY EXAMINER